PATIENT SPECIFIC INSTRUMENTATION

MATTHEW S. BERNARD, MD, AAOS

SOUTHEASTERN SPINE AND JOINT

CHATTANOOGA, TN

GOALS

- Understand the role of PSI in arthroplasty
- Improve efficiencies
- Improve alignment
- Decrease outliers

WHAT IS PSI?

- Dedicated Engineer
- Osteophytes included in block design
- Alignment, sizing, and rotation built into design
- 3D printed nylon cutting guides

Industry Leaders

- Zimmer-Persona
- Depuy-Trumatch
- Biomet-Signature
- Corin-optimized positioning system-HIP
- Smith&Nephew-Visionaire

ALTERNATIVES TO PSI

Conventional Instrumentation

- Placing a rod in the femoral canal
- Blood loss
- Tourniquet use
- Increased pain
- Increased soft tissue dissection
- Increased OR time

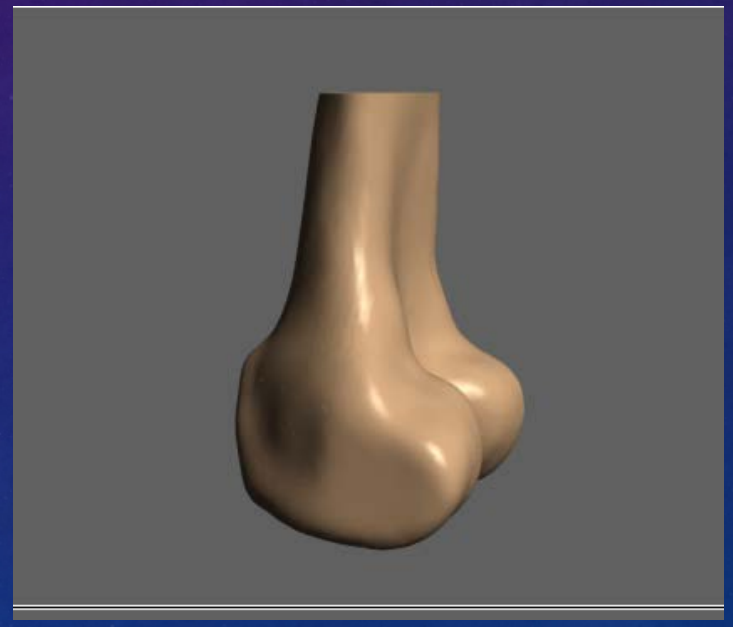
Robotic Assisted Surgery

- Expensive robot
- Increased surgical time
- OR storage
- Pin Placement complications

IMAGING

Full length x-rays

MRI or CT



ALIGNMENT

Mechanical vs. Anatomic axis

- Most lie between 3&7 degrees

Traditional instrumentation limitations

- Starting point
- Guide rod/femoral canal mismatch
- Blood loss

MRI PROTOCOL

- Each imaging center will need to be set up
- If done incorrectly patient will have to be scanned again

VISIONAIRE®
Patient Matched Instrumentation

A technology from smith&nephew

MRI protocol
Siemens Symphony 1.5T

MRI Acceptance Criteria

- Zero patient movement while performing scan sequence
- Pad knee well in coil to prevent even slight micro motion
- Knee joint centered to FOV showing equal portions of femur and tibia

ID	Smith & Nephew	Actual
Smith & Nephew ID	116	
Pulse Sequence	tse2dl_7	
Tesla	1.5	
Scan Plane	Sagittal	
Phase Direction	F/H	
TR	2800 or above	
TE	30-40	
Flip Angle	150	
Echo Train Length	7 or 8	
Bandwidth	199	
Concatenation	2, 1 if possible	
% Phase FOV	100%	
Slice Thickness (mm)	2	
Slice Gap (mm)	0	
Matrix (Frequency x Phase)	512 x 256(50%)	
Fat Saturation	OFF	
FOV (mm)	22 cm	
Acquisitions	2	
Approximate Scan Time	>10 min	
Phase oversampling between 50 – 80%		

Initial Set-up Instructions

1. Install and save the MRI sequence protocol to run for future cases as "Smith & Nephew Knee". Label 116 protocol.

Patient Positioning

1. Patient lying supine, feet first with leg in full extension and knee joint straight (up to a 15 degree bend is acceptable).
2. Restrict leg movement as much as possible, use padding and immobilization devices.
3. Knee joint centered to coil, position the coil as close to isocenter as possible.
4. Scan patient as close to isocenter as possible from left to right.

During the validation Smith & Nephew uses a specific phantom to measure the gradient linearity distortion at isocenter and maximum left position. For accuracy reasons; only a certain amount of distortion can be allowed for the VISIONAIRE process. If distortion values are higher than acceptable, then this scanner is rated Conditional for the Smith & Nephew scan. Only if the patient is scanned in the isocenter to +-30mm, (measured at the center of the knee), can it be guaranteed that the images are accurate. Please place the patient as close to isocenter as possible if scanning for VISIONAIRE. If the patient can't be placed into that position e.g. because of girth do not scan the patient and please inform the surgeon as well as your local Smith & Nephew sales representative.

Slice Positioning

See figures 1-3 for explanation of FOV centering and slice positioning. The scan must cover the entire bony knee; it is usually suggested to be 1 or 2 slices out of bone on either side. The images must be sagittal to the patient's knee in all 3 planes. Scan slices should be obliqued so that the resulting images are true sagittal, or perpendicular, to the joint line off of the coronal localizer. The slices should be obliqued off of the axial localizer so that the slices are perpendicular to a line drawn across the posterior femoral condyles. Off of the coronal localizer, the slices should be parallel to the femoral & tibial shafts.

Saving and Uploading Instructions for Test Images

1. Save DICOM files (Full DICOM format only) data to a CD directly from the MRI scanner or from PACS. Please ensure that no viewers are on this disk. Only actual scan data needs to be saved, no localizers are necessary.
2. Follow the test link in the email provided from Smith & Nephew.
3. Upload test MRI to Smith & Nephew website.

Delivering Patient Images After Site Approval

1. Your facility will receive a username and password once your site is approved.
2. Login to www.snVISIONAIRE.com. Click on the patient's name that is receiving the scans.
3. Zip all image data into one file.
4. Upload the zip file containing both the MRI and X-Ray images as described in the website tutorial.

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MRI PROTOCOL

- Once delivered engineers will subtract out all soft tissue
- All osteophytes retained
- The more irregular the shape, the better the fit

Patient Positioning

1. Patient lying supine, feet first with leg in full extension and knee joint straight (up to a 15 degree bend is acceptable).
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FOV 22cm/220mm

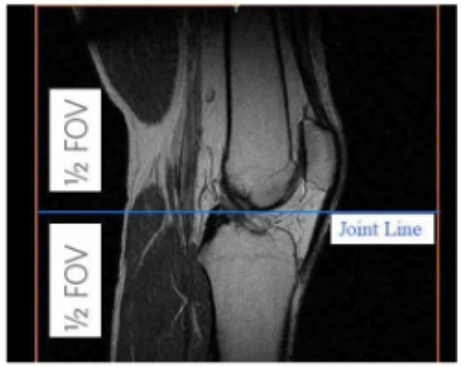


Figure 1 – Sagittal Localizer

The patient should be placed in the coil so that the resulting image has equal amounts of femoral and tibial shaft. Due to effective coil coverage some coil cut-off is expected but, this cut-off must be equally distributed and the joint space should be centered in the Field of View, (FOV). Please use sandbags, foam etc. to achieve this. This is essential to avoid patient motion on the resulting images.

FOV 22cm/220mm

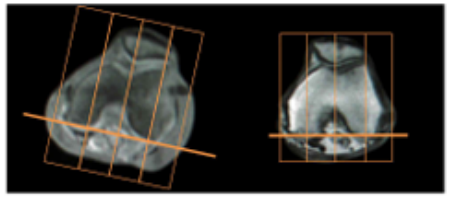


Figure 2 – Axial Localizer

The slices should be obliqued off of the axial localizer so that the slices are perpendicular to a line drawn across the posterior femoral condyles.

FOV 22cm/220mm

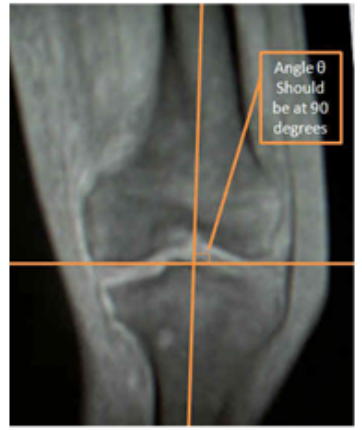


Figure 3 – Coronal Localizer

Knee joint centered to FOV showing equal portions femur and tibia. Line drawn parallel to distal femoral condyles is perpendicular to slice position. Slice coverage from R/L covers all knee bone anatomy.

Or

Draw line parallel to distal femoral condyles. Place slices 90 degrees (perpendicular) to this line.

Contact Info:
VISIONAIRE Hotline
1-800-262-3536
Option # 1
VISIONAIRESupport@smith-nephew.com

SURGICAL PRE-OP PLAN

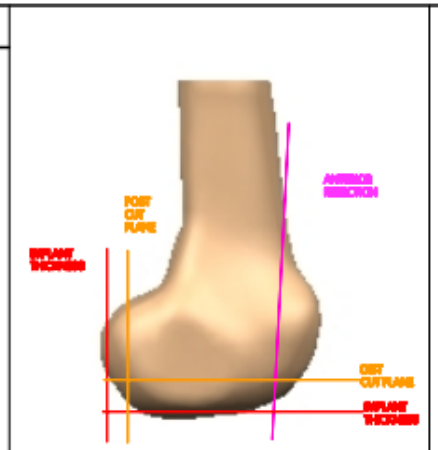
ANATOMY	RIGHT
SURGEON	DR. BERNARD, MATT
IMPLANT	JOURNEY II BCS
SURGERY DATE	FEBRUARY 15, 2023
X-RAY MEASUREMENTS	
PRE-OP FULL LEG DEFORMITY	9.3 VARUS°
MECHANICAL AXIS FEMUR VALGUS ANGLE	5.2°
TIBIA DEFORMITY	0.1°
FEMUR PART NO.	00249742V1 - NON-POROUS
DISTAL ALIGNMENT	5 DEGREES
A/P REFERENCE	ANTERIOR
EXTERNAL ROTATION	AP AXIS (WHITESIDE'S LINE)
ANTERIOR CUT PREFERENCE	STANDARD
DISTAL FEMORAL RESECTION	IMPLANT THICKNESS + 3MM
SIZE	4
BETWEEN SIZES	UPSIZE UNLESS ML OVERHANG
DISTAL MEDIAL RESECTION	8.0 mm
DISTAL LATERAL RESECTION	10.0 mm
DISTAL SULCUS RESECTION	4.0 mm
POSTERIOR MEDIAL RESECTION	7.5 mm
POSTERIOR LATERAL RESECTION	6.0 mm
TIBIA PART NO.	00249742V2 - NON-POROUS
PROXIMAL ALIGNMENT	MECHANICAL AXIS
EXTERNAL ROTATION	MEDIAL THIRD OF THE TIBIA TUBERCLE
POSTERIOR SLOPE	STANDARD 3 DEGREES
PLANNED INSERT THICKNESS	10MM RESECTION
MAXIMUM RESECTION DUE TO SEVERE DEFORMITY	INSERT THICKNESS +2MM
SIZE	3
IN BETWEEN SIZES	BEST FIT (SOME OVER/UNDER HANG ACCEPTABLE)
PROXIMAL MEDIAL RESECTION	4.5 mm
PROXIMAL LATERAL RESECTION	10.0 mm
RESECTION TO EMMINENCE	16.0 mm
NOTES: PATELLA MEASUREMENTS: S-I = 34 MM, M-L = 44MM.	

M/L VIEW

DISTAL RESECTION
- 8.0 mm off MEDIAL
- 10.0 mm off LATERAL
- 4.0 mm into SULCUS

POSTERIOR RESECTION
- 7.5 mm off MEDIAL
- 6.0 mm off LATERAL

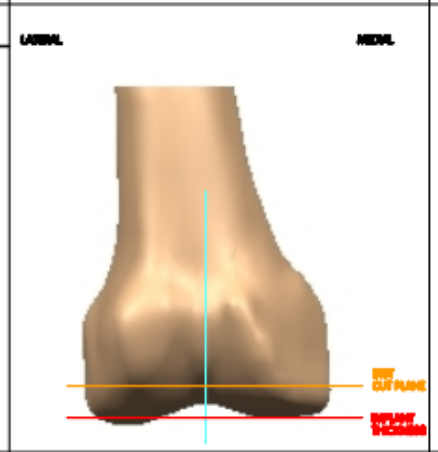
JBCS/JII DEEP FLEXION
- 8.5 mm off MEDIAL
- 6.5 mm off LATERAL



A/P VIEW

DISTAL RESECTION
- 8.0 mm off MEDIAL
- 10.0 mm off LATERAL
- 4.0 mm into SULCUS

VARUS/VALGUS ALIGNMENT
- 5 DEGREES

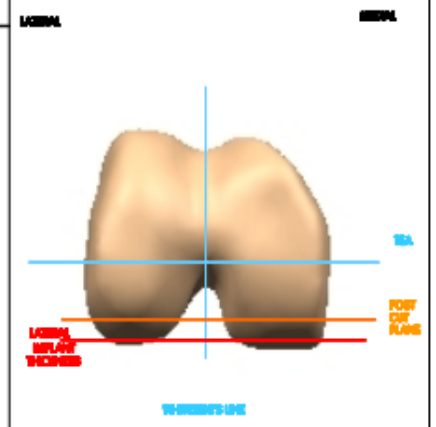


DISTAL VIEW - 90° FLEXION

EXTERNAL ROTATION
- AP AXIS (WHITESIDE'S LINE)
- RELATION to POSTERIOR RESECTION PLANE
  - TEA: .0°
  - PCA: 2.0° EXTERNAL

POSTERIOR RESECTION
- 7.5 mm off MEDIAL
- 6.0 mm off LATERAL

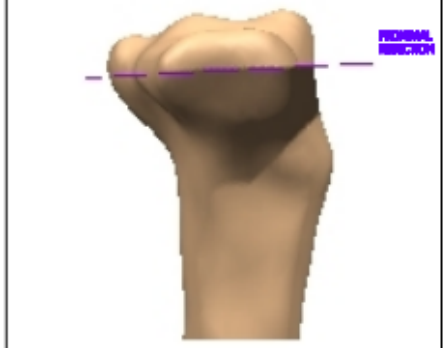
IMPLANT BOUNDARY
- MOST POSTERIOR HORIZONTAL LINE



M/L VIEW

POSTERIOR SLOPE

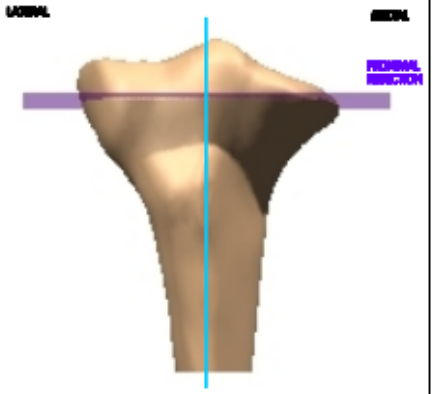
STANDARD 3 DEGREES



A/P VIEW

VARUS/VALGUS ALIGNMENT

MECHANICAL AXIS



PROXIMAL VIEW

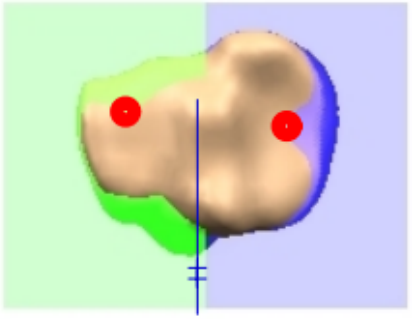
EXTERNAL ROTATION

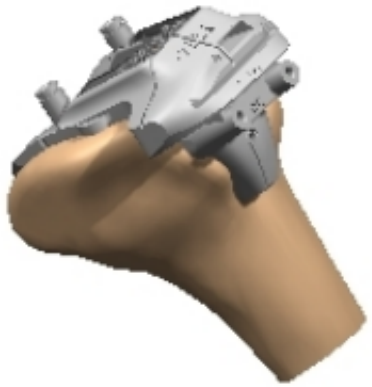
MEDIAL THIRD OF THE TIBIA TUBERCLE

PROXIMAL RESECTIONS

4.5 mm off MEDIAL

10.0 mm off LATERAL



FEMUR		
		
MEDIAL	DISTAL	LATERAL

TIBIA		
		
MEDIAL	ANTERIOR	LATERAL

X-RAY MEASUREMENTS

PRE-OP FULL LEG DEFORMITY
9.3 VARUS°

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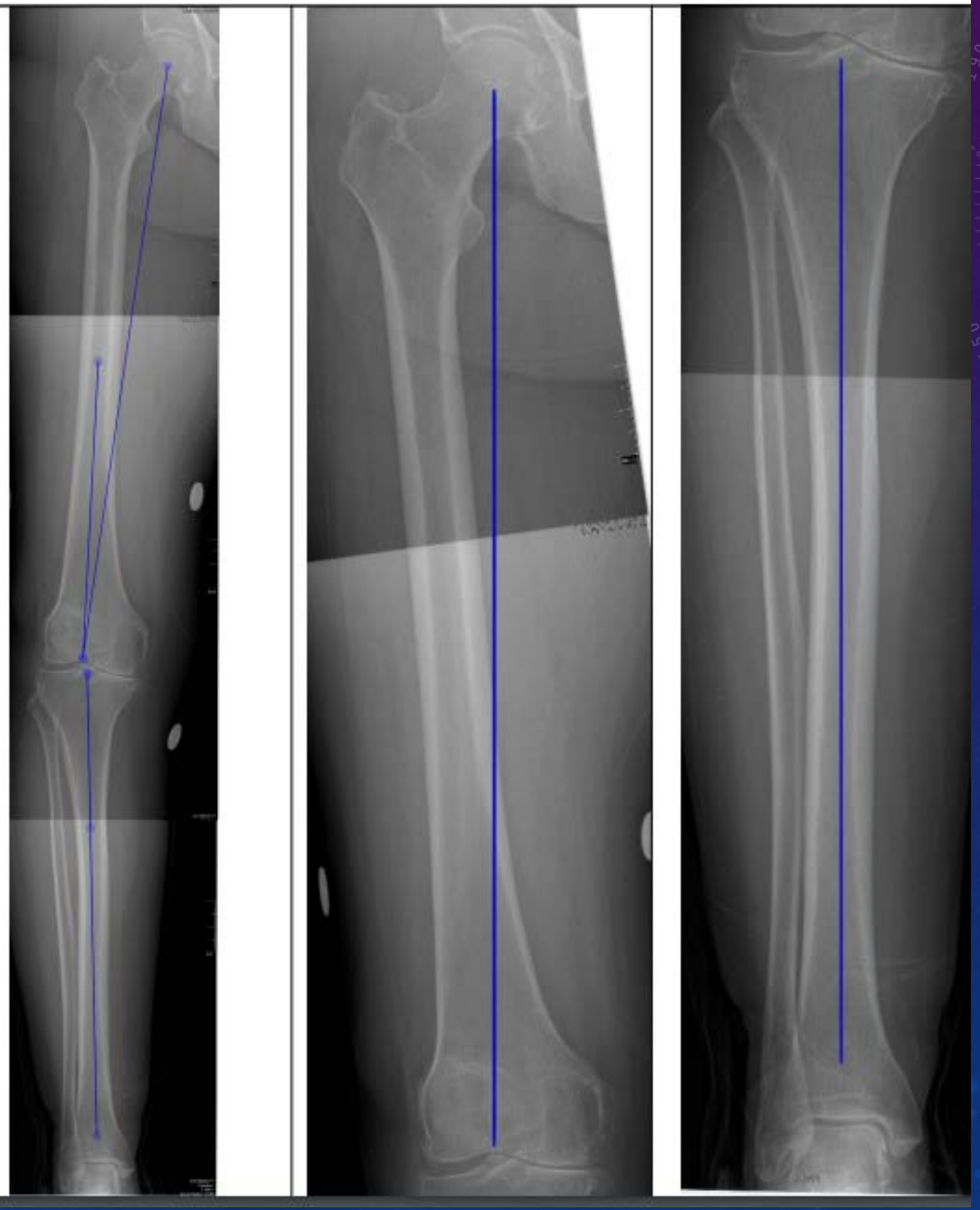
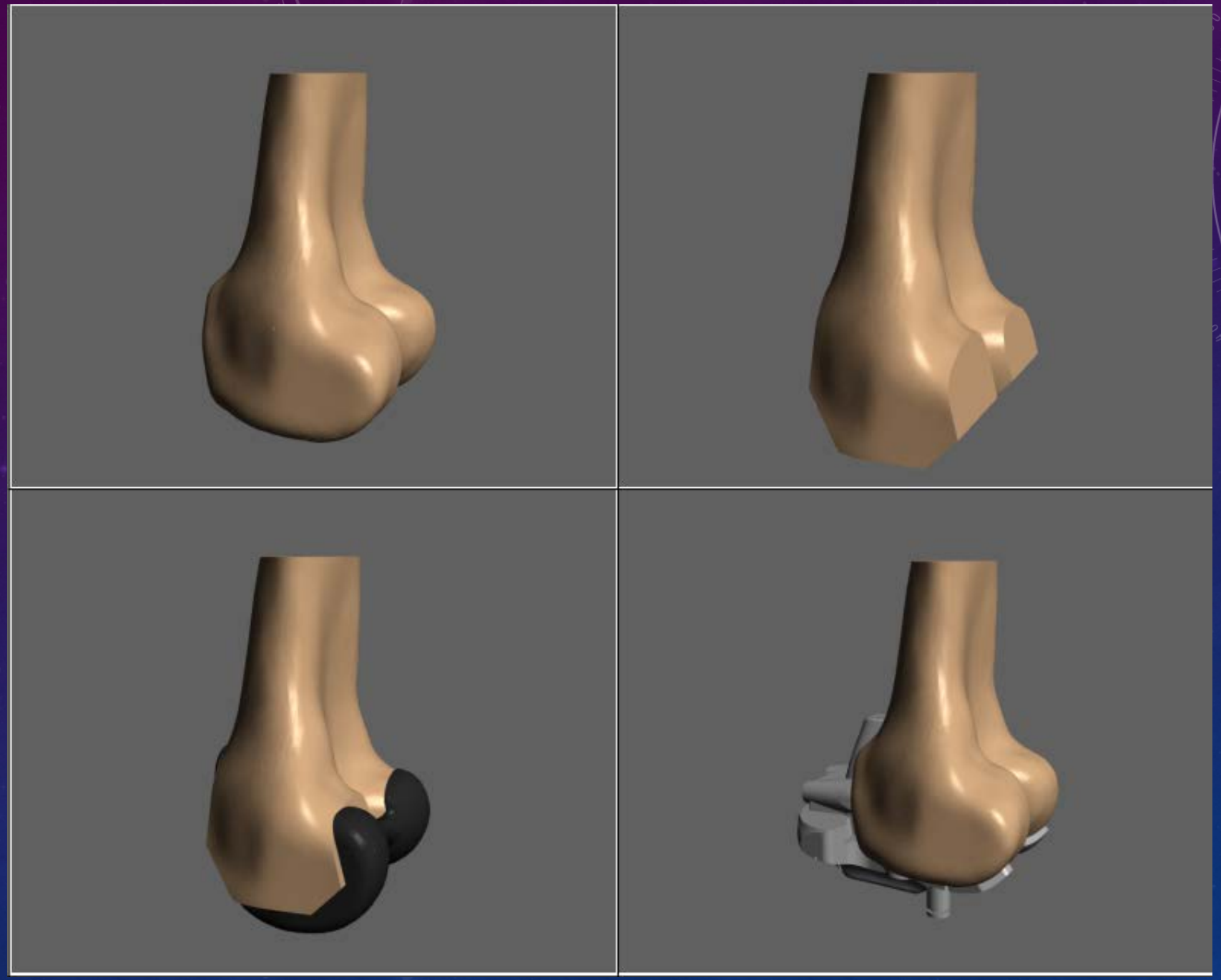
FEMUR VALGUS ANGLE
5.2°

TIBIA DEFORMITY
0.1°





EXTENSION

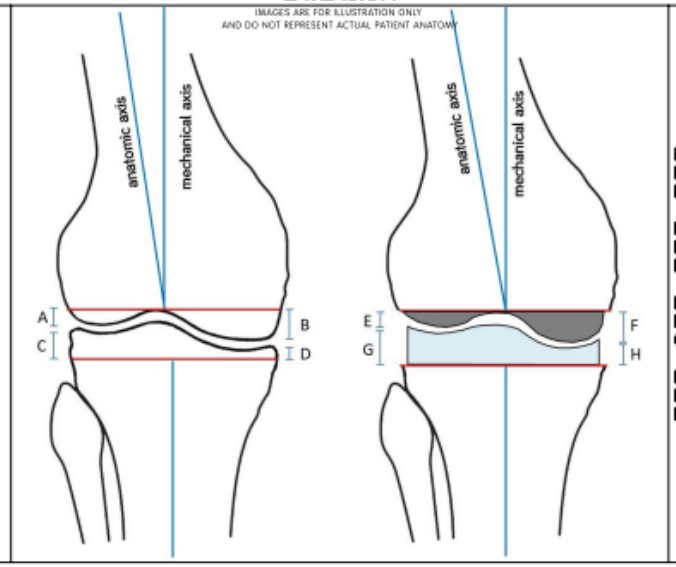
IMAGES ARE FOR ILLUSTRATION ONLY
AND DO NOT REPRESENT ACTUAL PATIENT ANATOMY

DISTAL LATERAL RESECTION
A: 10.00 mm

DISTAL MEDIAL RESECTION
B: 8.0 mm

PROXIMAL LATERAL RESECTION
C: 10.0 mm

PROXIMAL MEDIAL RESECTION
D: 4.5 mm



DISTAL LATERAL IMPLANT
E: 7.0 mm

DISTAL MEDIAL IMPLANT
F: 9.5 mm

PROXIMAL LATERAL IMPLANT
G: 11.6 mm

PROXIMAL MEDIAL IMPLANT
H: 9.6 mm

MEDIAL EXTENSION
Removed: 12.5 mm Replaced: 19.1 mm

LATERAL EXTENSION
Removed: 20.0 mm Replaced: 18.6 mm

FLEXION

IMAGES ARE FOR ILLUSTRATION ONLY
AND DO NOT REPRESENT ACTUAL PATIENT ANATOMY

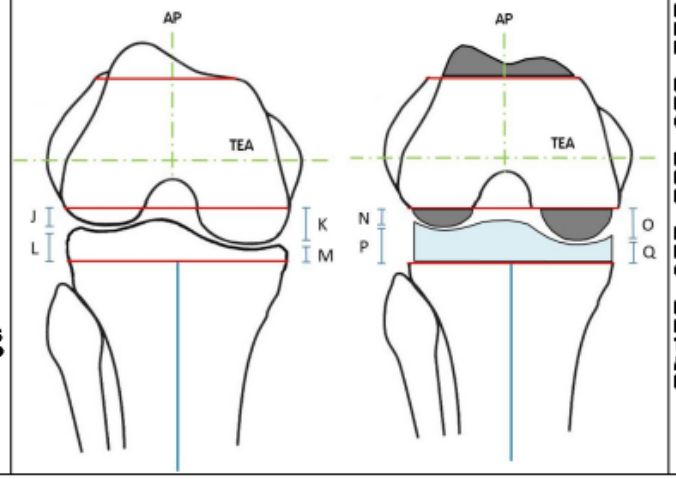
POSTERIOR LATERAL RESECTION
J: 6.50 mm

POSTERIOR MEDIAL RESECTION
K: 8.5 mm

PROXIMAL LATERAL RESECTION
L: 10.0 mm

PROXIMAL MEDIAL RESECTION
M: 4.5 mm

NOTE:
POSTERIOR RESECTIONS ARE MEASURED AT DEEP FLEXION



POSTERIOR LATERAL IMPANT
N: 7.4 mm

POSTERIOR MEDIAL IMPLANT
O: 9.0 mm

PROXIMAL LATERAL IMPLANT
P: 11.6 mm

PROXIMAL MEDIAL IMPLANT
Q: 9.6 mm

NOTE:
POSTERIOR IMPLANT THICKNESSES ARE MEASURED AT DEEP FLEXION

MEDIAL FLEXION
Removed: 13.0 mm Replaced: 18.6 mm

LATERAL FLEXION
Removed: 16.5 mm Replaced: 19.0 mm

PLACING FEMORAL GUIDE

PLACING TIBIAL GUIDE

OUTCOMES

- Meta analysis of 29 random controlled trials with 2487 knees
- PSI reduced the blood loss and improved KSS
- MRI based PSI reduced operative time and risk of malalignment compared with CT based PSI and conventional instrumentation

Hindawi
BioMed Research International
Volume 2020, Article ID 2164371, 12 pages
https://doi.org/10.1155/2020/2164371

Review Article

Patient-Specific or Conventional Instrumentations: A Meta-analysis of Randomized Controlled Trials

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Objective. To conduct a meta-analysis of randomized controlled trials (RCTs) to compare knee arthroplasty with patient-specific instrumentation (PSI) with the conventional instrumentation (CI). *Methods*. RCTs were selected in PubMed and Embase from 2012 to 2018. Key data extracted included malalignment of mechanical axis, blood loss, surgical time, Oxford Knee Score (OKS), Knee Society Score (KSS), length of stay, and complications. Subgroup analysis was also performed regarding different PSI systems and different image processing methods. *Results*. 29 RCTs with 2487 knees were eligible for the meta-analysis. Results showed that PSI did not improve the alignment of the mechanical axis compared with CI, but MRI-based PSI and Visionaire-specific PSI decrease the risk of malalignment significantly ($P = 0.04$ and $P = 0.003$, respectively). PSI reduced operative time ($P = 0.03$) and blood loss ($P = 0.002$) and improve the KSS ($P = 0.02$) compared with CI, but for CT-based PSI, the difference of operative time becomes insignificant. PSI showed no significant difference with CI regarding risk of complication, length of stay in hospital, and functional outcomes of OKS. *Conclusion*. PSI reduced the blood loss and improved KSS. MRI-based PSI reduced operative time and risk of malalignment of mechanical axis compared with CT-based PSI. Moreover, Visionaire-specific PSI achieves better alignment result of the mechanical axis than other systems.

OPERATING ROOM EFFICIENCIES

Traditional TKA

- Universal Base Tray
- Finishing + Impactor Tray
- Universal Alignment Tray
- + 8 Implant Trays to include all sizes
- Instrument Tray
- 12 Total Trays

PSI TKA

- Universal Base Tray
- Finishing + Impactor Tray
- Patella Prep Tray
- Sizing Tray
- Instrument Tray
- 5 Total Trays

OPTIMIZING INSTRUMENTATION

- One tray
- 62 instruments
- Lighter tray
- Less sterilization
- Quicker turnover

OPTIMIZING INSTRUMENTATION

- 3 company trays
- Size specific half pans
- Peel packed one offs

“Studies have shown for every 15 minute increase in surgical time over 60 minutes there is a 9% increase in infection rates.”

Namba, Robert 5, et AI. Risk Factors Associated with Deep Surgical Site InfectionsAFter Primary Total Knee Arthroplasty. An Analysis of 56, 216 Kneese. JBJ

VISIONAIRE OPTIMIZES THE OR

VISIONAIRE EFFIECENCES

- Shorter operating room time – 9.6% less time
- Shorter operating room turnover time – 42% less time
- Shorter tourniquet -20.2 % less time

1 Hicks C, Saunders C. VISIONAIRE More efficient for total knee arthroplasty (TKA) than conventional techniques. Evidence in focus. Systemic literature of meta analysis *Compared to conventional techniques

VISIONAIRE COST SAVINGS CASE STUDY

UNITED HOSPITAL ST. PAUL, MINNESOTA

Conventional Instrumentation

- 9-11 trays per TKA needed
- 2 back tables required
- Average Set Up Time: 57 minutes
- 45+ trays required for busy days with 5+ TKAs scheduled
- Space is limited and volume is increasing at United Hospital

VISIONAIRE Instrumentation

- 1 tray + 6 peel packed instruments (FASTPAK) per TKA needed
- Easy set up & tear down with 1 back table
- Average Set Up Time: 41 minutes
- Less Sterlization
- Less risk of contamination
- Streamline cases = happy hospital staff
- Less instrumentation & inventory required to live at the hospital

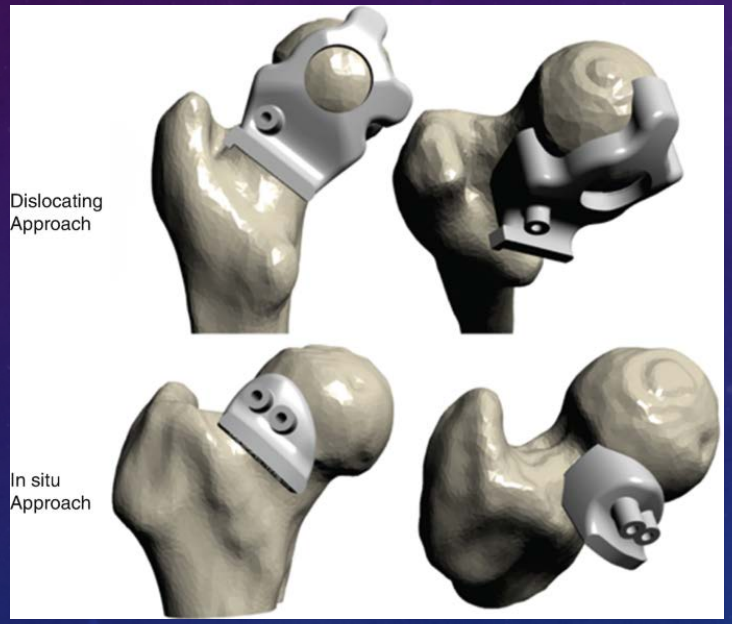
WHAT'S NEXT?

FASTPACK Single Use Instrumentation

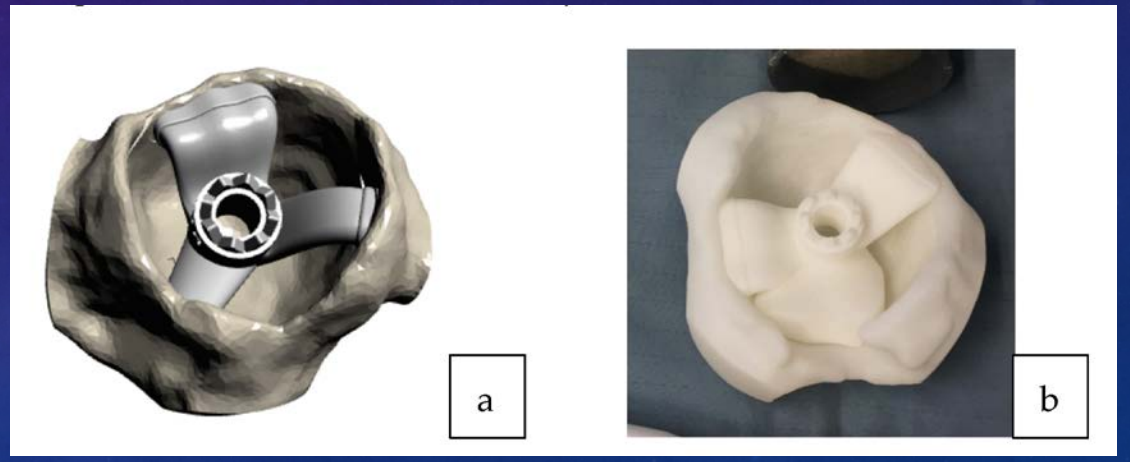
- Size Specific instruments are individually sterile packaged
  - Femoral ream through trial with cam
  - Tibial base plate
  - Tibial punch
  - Trial Poly inserts

HIP PSI

Femoral cutting guide



Acetabular guide



CORIN HIP PSI

- Dynamic 3D model
- Understanding spineopelvic relationships
- Redefining the safe zone
- Implant sizing based on bone density
- Restoration of leg length and offset

THANK YOU, QUESTIONS?